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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. 1.53(b)

Box Patent Application  
Assistant Commissioner for Patents  
Washington, DC 20231

Express Mail Label No. EL293690907US  
Date of Deposit October 28, 1999



Sir:

This is a request for filing a **continuation** application under 37 C.F.R. 1.53(b)

of

Applicants: Steinfeldt-Jensen et al.

Title: Injection Syringe

21 pages of specification 5 sheets of drawings

2 sheets of Declaration and Power of Attorney

[x] The filing fee is calculated as follows:

Basic Fee:	\$760.00
Total Claims: $8 - 20 = 0 \times 18 =$	\$0
Independent Claims: $1 - 3 = 0 \times 78 =$	\$0
Total Fee:	\$760.00

Priority of Danish application no. PA 1998 00130 filed on January 30, 1998 is claimed under 35 U.S.C. 119. A certified copy was submitted with USSN 09/238,849.

Priority of U.S. provisional application no. 60/073,820 filed on February 5, 1998 is claimed under 35 U.S.C. 119.

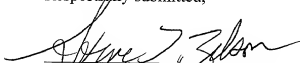
The benefit of application no. 09/238,849 filed on January 28, 1999 in the U.S. is claimed under 35 U.S.C. 120.

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be \$760, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: October 28, 1999



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

Box Patent Application  
Assistant Commissioner for Patents  
Washington, DC 20231

Re: U.S. Patent Application for  
Title: Injection Syringe  
Applicants: Steinfeldt-Jensen et al.



Sir:

Express Mail Label No. EL293690907US

Date of Deposit : October 28, 1999

I hereby certify that the following attached paper(s) or fee

1. Filing Under 37 C.F.R. 1.53(b) (in duplicate)
2. Patent Application
3. Copy of executed Combined Declaration and Power of Attorney
4. Preliminary Amendment
5. 5 Sheets of Formal Drawings
6. Information Disclosure Statement
7. Form PTO-1449

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Gina Maldonado

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Steinfeldt-Jensen et al.

Serial No.: To be assigned

Group Art Unit: To be assigned

Filed: October 28, 1999

Examiner: To be assigned

For: Injection Syringe

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

**IN THE SPECIFICATION:**

At page 1, before the first line, insert

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application serial no. 09/238,849 filed January 28, 1999 (now allowed), which claims priority under 35 U.S.C. 119 of Danish application PA 1998 00130 filed January 30, 1998 and of U.S. provisional application no. 60/073,820 filed February 5, 1998, the contents of which are fully incorporated herein by reference.--

**IN THE CLAIMS:**

Please amend claim 3 as follows:

At line 1, delete "or 2".

Please amend claim 5 as follows:

At line 1, delete "anyone of the preceding claims" and insert --claim 1--.

Please amend claim 7 as follows:

At line 1, delete "2, 3, or 4".

Please amend claim 8 as follows:

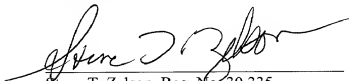
At line 1, delete "2, 3, or 4".

### REMARKS

This amendment is submitted to correct improper multiple dependent claims.

Since only dependencies are altered, there is no new matter added, and entry of the amendment is respectfully requested.

Respectfully submitted,



Date: October 28, 1999

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An injection syringe

5 The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

30 The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts  $360^\circ$  must be calculated by adding the number pointed at

5 on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line

10 on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

15 In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a

20 dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inro-

25 tatable in a housing. This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing. This pen fulfils all the

30 objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

- 5 This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

10

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

- 15 a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

20

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

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which syringe according to the invention is characterised in that

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a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal di-



rection in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

- During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

- When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctance is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

- According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

- The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

- A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

- The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

- 10 In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

- 15 In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the unidirectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

- 20 In the last mentioned embodiment of the injection syringe the dose scale drum may be mounted rotateable but not axially displaceable on the injection button. When the dose scale drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a

dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

- 5 In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during  
 10 the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of  
 15 the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the uni-directional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is re-  
 20 turned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

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In the following the invention is described in further details with references to the drawing, wherein

Figure 1 shows a front view of an embodiment of an injection syringe according to  
 30 the invention,

Figure 2 shows a sectional view along the line II-II in figure 1,

Figure 3 shows in a reduced scale an exploded view of the syringe in figure 1,

- Figure 4 shows a sectional view along the line IV-IV in figure 1,
- Figure 5 shows a sectional view along the line V-V in figure 1,
- 5 Figure 6 shows a front view of another embodiment of an syringe according to the invention,
- Figure 7 shows a sectional view along the line VII-VII in figure 6,
- 10 Figure 8 shows in a reduced scale an exploded view of the syringe in figure 6,
- Figure 9 shows a sectional view along the line IX-IX in figure 6,
- 15 Figure 10 shows a sectional view along the line X-X in figure 6.
- Figure 11 shows a sectional side view of another embodiment of a syringe according to the invention,
- 20 Figure 12 shows a sectional side view perpendicular to the view in figure 11,
- Figure 13 shows in a reduced scale an exploded view of the syringe in figure 11 and 12,
- 25 Figure 14 shows a sectional side view of the dose setting part of another embodiment of a syringe according to the invention,
- Figure 15 shows a sectional side view of still another embodiment of a syringe according to the invention,
- 30 Figure 16 shows a sectional side view perpendicular to the view in figure 15,
- Figure 17 shows in a reduced scale an exploded view of the syringe in figure 15 and 16,

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

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Figure 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set doses. Figure 3 shows an exploded view of this syringe and the figures 2, 4 and 5 sectional views taken along different lines in figure 1.

- 10 The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferential groove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be
- 15 rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of

20 the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

- The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.
- 25

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In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At

least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical groove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31

circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in figure 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a reluctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted dose is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the figures 6-10. Elements corresponding to elements in the embodiment described with references to the figures 1-5 are provided with the same reference numbers. Different from the embodiment in figure 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction. Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling is influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is



moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.

A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to figure 1 is in the embodiment according to figure 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39 in a cylindrical outer wall of the button 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

The embodiment shown in figure 11, 12 and 13 has the housing 1 with the window 18. The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1. Further protrusions 44 on the ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal re-

cess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided  
5 with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable an non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the  
10 proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is longitudinally displaceable in the bushing 53 but inrotatable relative to said bushing and consequently relative to the housing 1. The guide member has at its distal end an annular end wall 57. The part 51 of the nut member 48 is passed through the opening of said end wall 57 and has a bead 58 gripping into a circumferential inner recess in the  
15 wall of annular opening through said end wall to keep the bushing 53 secured to said part 51 so that this part can be rotated but not axially displaced in relation to the bushing 53. The scale drum 17 is journaled on the nut member 48 and is held on this nut member by having a flange 90 held between the end wall 57 of the guide member 56 and the shoulder formed where the part 51 connects to the nut member 48.

20 The button 23 is held rotatably on the guide member 56 which has a ring bead 59 engaging a circumferential recess 60 in the inner wall of the button 23 which recess 60 is somewhat broader than than the bead 59 so that the button in excess of being rotatable on said bushing 53 can be axially displaced a distance defined by the width of the recess 60 relative to  
25 the width of the bead 59. The button 23 is coupled to the nut member 48 by internal ribs 61 in the tubular part 52 engaging slots 62 in the proximal part of the part 51 of the nut member 48. This coupling forces the button 23 and the nut member 48 to follow each other in rotational movements but allow a minor relative axial displacement.

30 The proximal end surface of the guide member 56 has one or more axially directed protrusions 63 which can co-operate with radial recesses 64 in the bottom of the button 23, but mainly a biasing keeps these recesses and protrusions out of engagement. Further the guide member has at its proximal end at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of the button to produced a click sound each time the

button is rotated relative to the bushing so that the protrusion jump from one recess to the neighbour recess.

- To set a dose the button 23 is rotated in a clockwise direction. This rotation is due to the
- 5 coupling between the ribs 61 and the slots 62 transmitted to the nut member 48 which is then screwed in distal direction along the driver tube 45 which is held inrotatably in the housing due to the reluctans of the pawl 13 to move along the pawl teeth in the member 40. The movement of the nut member 48 in proximal direction makes the scale drum 17, the
- 10 guide member 56, and the tubular part 52 with the button move in proximal direction so that the button is elevated over the end proximal end of the housing 1. A to high set dose can be reduced by rotating the button in an anti clockwise direction.

- During the rotation of the button the radial protrusion 65 of the guide member 56 clicks from one axial recess 66 to the other. The distance between can appropriately be chosen so that
- 15 a click corresponds to a changing of the set dose by one international unit up or down. Due to engagement between the helical groove on the cylinder wall of the scale drum and a helical rib on the inner wall of the housing the movement of the dose scale drum 17 will rotate and displace said drum so that the set dose is shown in the window 18.
- 20 When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

- 25 To inject the set dose the button 23 is pressed. Thereby the bias keeping the protrusions 63 and the recesses 64 out of engagement is overcome and the said engagement is established. The button 23 is now locked relative to the guide element 56 which is again locked against rotation relative to the bushing 53 and consequently relative to the housing 1. The coupling between the tubular part 52 and the nut member 48 makes this nut member inro-
- 30 tatable relative to the housing so an axial movement of said nut member in a distal direction will due to the not self locking thread coupling between this nut element and the driver tube 45 make this driver tube 45 rotate in a clockwise direction and due to the key/groove coupling between the driver tube 45 and the piston rod 6 said piston rod will be screwed through the end wall 4 further into the ampoule holder compartment. The locking of the button 23

against rotation during the injection ensures that the set dose is not inadvertently changed during the injection.

5 In the embodiment shown in figure 14 separate buttons are provided for the dose setting and the injection. Corresponding to previously described embodiments this one has a housing 1 and a driver tube 67 which is rotatable in only one direction due to a pawl which engage pawl wheel teeth in a part secured in the distal end of the housing. Trapping of the pawl between the member 40 and a ring shaped wall 46 in the housing fixes the driver tube against axial movement. On the outer wall of the driver tube 67 an axial rib 68 is provided which rib engages an axial recess 69 in a tubular injection element 70 to transmit rotation of said injection element to the driver tube 67.

15 At the proximal end of the housing 1 a dose setting button 71 is mounted so that this button can be rotated but not axially displaced relative to the housing 1. This is obtained by the fact that the dose setting button 71 on a part fitting into the housing has a ring shaped bead 72 which engages a mating circumferential recess 73 in the inner wall of the housing. Outside the housing the dose setting button has a part having a diameter corresponding to or being larger than the diameter of said housing which part can be provided with axial ribs 74 to ensure a good grip by the setting of a dose. The dose setting button 71 has a central bore the inner wall of which has a helical recess 75 engaging a helical rib 76 provided on the outer wall of the proximal part of the injection element 70 which element passes through the bore of the dose setting button 71. The outer wall of the distal part of the injection element 70 forms a journal for the scale drum 17 which through an outer helical recess engaged by an internal helical rib 16 in the housing is rotated to show the set dose in the window 18 when the scale drum is displaced axially in the housing. The proximal end of the injection member is terminated by an end wall 77 which carries an injection button 78 which is by a pivot pin 79 journaled in a central bore in said end wall 77.

30 To set a dose the dose setting button 71 is rotated in a clockwise direction. As the injection member is kept non rotatable by its coupling to the driver tube 67 the collaboration between the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will screw the injection element out through the dose setting button so that the injection button 78 is lifted up from the proximal end of the housing. Although the driver tube 67 with its pawl can be rotated in the clockwise direction

an initial torque is needed which is larger than the torque transmitted from the dose setting button to the injection element.

To inject a set dose the injection button 78 is pressed and the injection element is moved  
 5 back into the housing. The co-operation of the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will now make the injection element rotate in a clockwise direction and if only the injection button is pressed hard enough a torque is produced large enough to overcome the initial reluctance of the pawl mechanism against rotation in said clockwise direction.

10

The separation of the dose setting button 71 and the injection button 78 makes it less likely that the dose setting button is inadvertently operated during the injection.

Figure 15, 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of  
 15 a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The  
 20 piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.

A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical  
 25 rib 16 along the inner wall of the housing 1. At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip.

A bushing 82 having a flange 83 at its proximal end and having a pair of opposite longitudinal  
 30 slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.

- In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment. At its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.

The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that a limited movement of the bushing in the scale drum is allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other. An injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.

- When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing. The bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation. Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit. During the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.

When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing. The bushing will rotate the driver tube 85 in an anticlockwise direction which

the pawl mechanism reluctantly allows an the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2.

- 5 By this device the risk for inadvertent operation of the dose setting button 81 during the injection is eliminated. Further the device consist of a minimum of parts whereby the manufacturing is made easy.

CLAIMS

1. An injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide mating the not circular cross-section of the piston rod to allow axially displacement but not rotation of the piston rod in relation to said piston rod guide, and

b) a nut member which is not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that an initial reluctance set large



enough to resist a torque exerted on the coupling by the dose setting has to be overcome before rotation takes place.

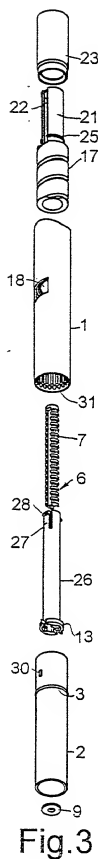
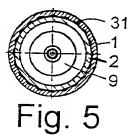
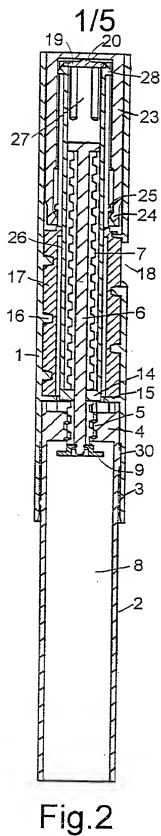
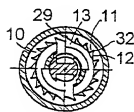
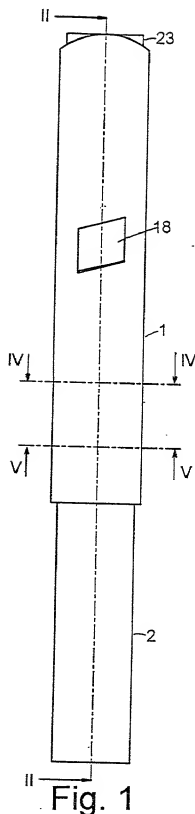
2. An injection syringe according to claim 1, characterised in that a click coupling providing  
5 an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.
3. An injection syringe according to claim 1 or 2, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a  
10 ramp shaped trailing edge.
4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.
- 15 5. An injection syringe according to anyone of the preceding claims, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing, and that the dose scale drum and is coupled to the injection button to be moved axially with this button.
- 20 6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.
- 25 7. An injection syringe according to claim 1, 2, 3, or 4 characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.
- 30 8. An injection syringe according to claim 1, 2, 3 or 4, characterised in that the piston rod guide is mounted in a driver tube in which tube the piston rod is axially displaceable but is rotated with said tube, and that the not self locking thread connection which determines the lifting of the injection button is provided between the driver tube and a part which is axially displaceable with the injection button.

ABSTRACT

In an injection syringes comprising a housing (1), a piston rod (6) with a not circular cross-section and an outer thread (7), a piston rod drive comprising a piston rod guide (85) mating  
5 the cross-section of the piston rod (6) and a nut (4) which is not axially displaceable and mates the thread (7) of the piston rod (6) to form a self locking thread connection, and a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element (81) is screwed out to project from the housing (1) and which thread connection by axial returning of the injection button (88)  
10 transforms this axial movement into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place said reluctance being large enough to resist torques exerted during the dose setting.

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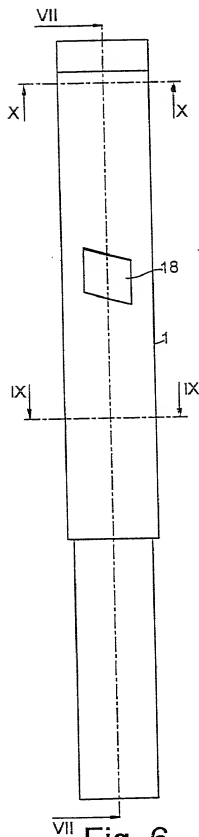


Fig. 6



Fig. 9

2/5

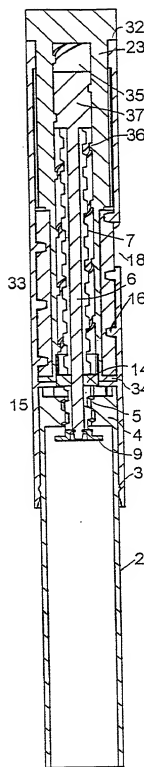


Fig. 7

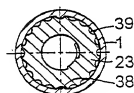


Fig. 10

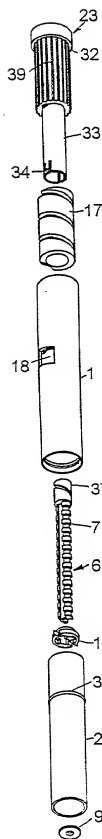


Fig. 8

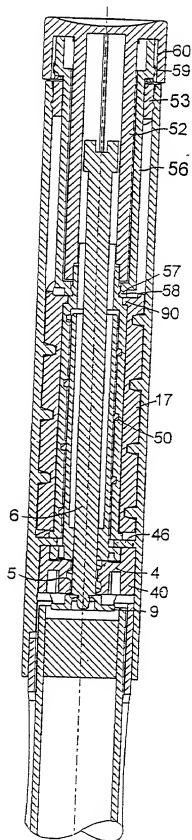


Fig. 11

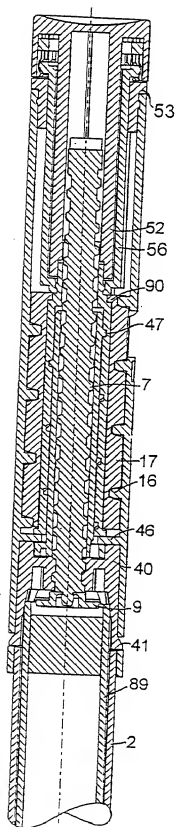


Fig. 12

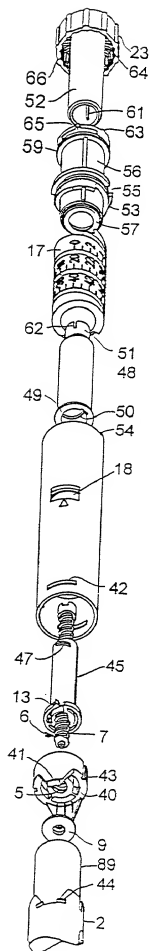


Fig. 13

4/5

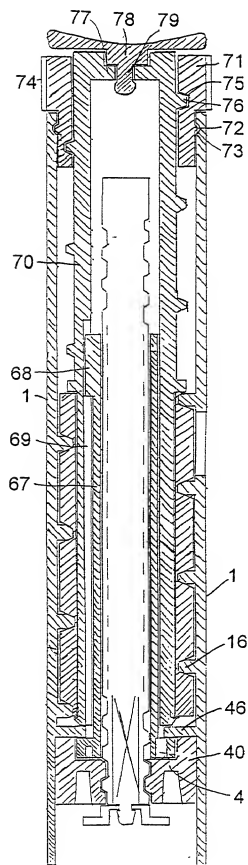


Fig. 14

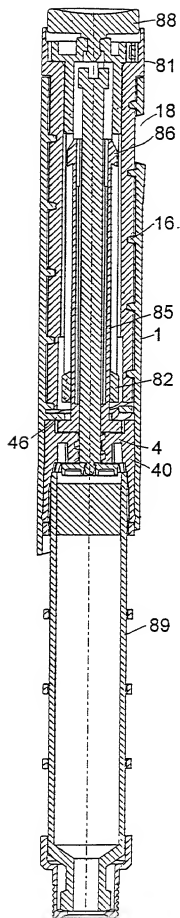


Fig. 15

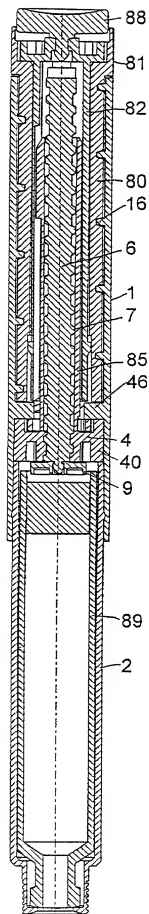


Fig.16

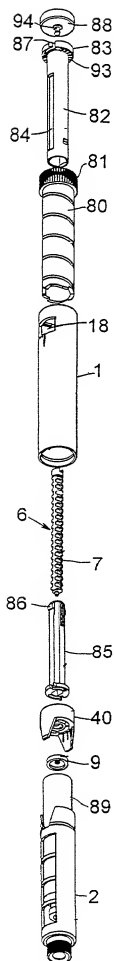


Fig. 17

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

An Injection Syringe

the specification of which (check only one item below):

☐ is attached hereto

☒ was filed as United States application

Application No. to be assigned

on January 28, 1999

and was amended

on

☐ was filed as PCT international application

Number

on

and was amended under PCT Article 19

on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

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COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
DK	PA 1998 00130	30 January 1998	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
US	60/073,820	5 February 1998	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
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			<input type="checkbox"/> YES <input type="checkbox"/> NO



**COMBINED DECLARATION FOR PAT APPLICATION AND POWER OF ATTORNEY**  
(Includes Reference to PCT International Applications)

Attorney's Docket Number  
5472.200-US

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U.S. FILING DATE

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FILING DATE

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ASSIGNED (if any)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.  
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Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Date 9/2 - 1999	Date 9/2 - 1999	Date